UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 01-12257-PBS (Original Central District of California No. 03-CV-2238)
THIS DOCUMENT RELATES TO: State of California, *ex rel.* Ven-A-Care v. Abbott Laboratories, Inc., *et al.* CASE #: 1:03-cv-11226-PBS	Judge Patti B. Saris

DEFENDANTS' REPLY
TO PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' JOINT MOTION TO DISMISS THE FIRST AMENDED COMPLAINT-IN-INTERVENTION

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PRELIMINARY STATEMENT

As set out in Defendants' Motion to Dismiss, all five counts in Plaintiffs' First Amended Complaint In Intervention ("Amended Complaint") fail to state a claim under Rule 12(b)(6) -- let alone with the specificity required by Rule 9(b). Plaintiffs' 40-page Response, while a valiant effort to backfill the inadequacies of the Amended Complaint, falls well short of the mark.

Plaintiffs' Response does not (and cannot) deny that, for decades, California *chose* to reimburse its Medicaid providers for pharmaceuticals based on AWP or Direct Price ("DP"). Not once over the course of decades did California attempt -- by statute, regulation, or otherwise -- to define those terms as anything other than the "list price" published by various industry publications. There is also no dispute that California knew, as did the federal government, that pharmaceuticals were being bought and sold for prices lower than AWP or DP. Nevertheless, California chose AWP or DP as its reimbursement benchmark.[1]

California now apparently regrets its choice; having decided it should have paid less (though exactly how much less is nowhere stated). Buyer's remorse, however, transmutes nothing Defendants did into conduct actionable under the California False Claims Act ("CFCA"). Plaintiffs have not pleaded (and cannot plead), that (1) a false claim was actually presented; (2) California unknowingly paid any such false claim; or (3) each Defendant acted with the requisite scienter. And, even if Plaintiffs could state the requisite elements of an actionable CFCA claim, simply incanting the words "false," "fraud," and "scheme" over and

[1] Knowing that the public record clearly demonstrates that Defendants never had the requisite scienter for a violation of the California False Claims Act and that California approved and paid claims with full knowledge that the pricing information published by various industry publications did not equate to actual sales prices (net all possible discounts), Plaintiffs implore the Court to close its eyes to matters in the public domain. Their request should be denied. Defendants have filed, concurrently with this Reply, a separate *Response to Plaintiffs' Objections Pursuant To Rule 201(2) Of The Federal Rules of Evidence To Judicial Notice Of Facts And Conclusions Set Forth In Defendants' Motion to Dismiss*.

over again does not satisfy the requirements of Rule 9(b). For these and other reasons, as set out in Defendants' Motion to Dismiss and below, the Amended Complaint should be dismissed.

ARGUMENT

I. PLAINTIFFS FUNDAMENTALLY MISCHARACTERIZE CALIFORNIA'S ROLE IN REIMBURSING FOR PHARMACEUTICALS; IT WAS CALIFORNIA, NOT DEFENDANTS, THAT DECIDED TO REIMBURSE BASED ON PUBLISHED LIST PRICES.

At bottom, Plaintiffs' Response demonstrates that their Amended Complaint and their allegations of "false claims" rest on a fundamental mischaracterization of how Medi-Cal reimbursement works. To be clear: it was California -- not Defendants -- who chose to use AWP and DP as reimbursement benchmarks for Medi-Cal. Nor could it be any different: Federal law *requires* that *California* (not Defendants) set *California's* reimbursement rate at Estimated Acquisition Cost ("EAC"), which it defines as *California's* best estimate of providers' acquisition cost of the drugs. *See* 42 C.F.R. § 447.301. Thus, federal law requires *California* to make its own best estimate of what providers were paying for pharmaceuticals and to set its Medicaid reimbursement level at that figure.

Rather than conducting any in-depth research, requiring providers to report their purchase prices for pharmaceuticals, or otherwise attempting to discharge its federal duties with any diligence, California took the easy route: It decided to simply use certain list prices published in easily available compendia -- AWP and DP -- as its "estimation" of what providers pay for pharmaceuticals. (*See* Compl. ¶¶ 27, 35.) Contrary to Plaintiffs' assertions (*see* Resp. at 1), not a single statute or regulation, either California or federal, requires drug manufacturers to report any pricing information to pricing compendia or that California use the prices published by such compendia as a basis for determining Medi-Cal reimbursement. Nor can Plaintiffs cite a single statute or regulation stating that Defendants' drugs "would not be reimbursed unless the

Defendants reported or caused their prices to be reported to [pricing] compendia." (*See* Resp. at 1-2.) Instead, California simply adopted the AWP and DP listed in the compendia as its "best estimate" of what providers pay for drugs.[2]

The terms AWP and DP, however, have been used for decades by the pharmaceutical industry to represent *list prices* for Defendants' drugs, as California well knew. And California did not, when it decided that these terms were California's best estimate of what providers pay for pharmaceuticals, attempt to regulate those terms by tying them to specific market transactions. Indeed, California chose to codify the pharmaceutical industry's understanding of the terms by defining AWP and DP as the price listed in pricing compendia. CAL. WELF. & INST. CODE § 14105.45. That is not a criticism; California's choice may have been a reasonable one -- for example, California may have desired that its higher reimbursement levels for drugs be used to offset lower reimbursement levels for services, in order to encourage providers to continue to dispense both Medicaid drugs and services. *See* 42 U.S.C. § 1396a(a)(30)(A). But, whatever the reason for California's choice, it had consequences. California cannot now, after racking up years of purported "damages," allege that AWP and DP *should* have meant something other than what was defined in California's own regulations for decades.

With the foregoing in mind, it becomes clear just how futile Plaintiffs' attempts to stretch the California *False Claims* Act to fit this case really are.

[2] Plaintiffs' claim that Defendants make it "extraordinarily difficult [for California] to discover the true acquisition costs" of Defendants' drugs is simply wrong. (Resp. at 2.) California law specifically authorizes California to compel providers to provide it with invoices showing the exact amount they paid for Defendants' drugs. *See* 22 C.C.R. § 51476 (requiring providers to maintain records, including copies of "original purchase invoices" for drugs furnished to Medi-Cal beneficiaries, and to make such records available to California officials upon request). Moreover, California negotiates directly with manufacturers to obtain supplemental rebate contracts that are generally based on the manufacturer's "best price." *See* CAL. WEL. & INST. CODE § 14105.33.

II. ALL COUNTS IN THE AMENDED COMPLAINT SHOULD BE DISMISSED PURSUANT TO RULE 12(B)(6).

A. All Of Plaintiffs' Claims Fail To Allege the Falsity Required By The CFCA.

While Plaintiffs allege time and again that Defendants made a fraudulent statement, or intended to defraud California, bald allegations do not state a CFCA claim. Nor do (or can) Plaintiffs properly allege the three distinct elements of falsity in a CFCA claim: (1) the submission of a claim that is false; (2) that California was actually defrauded (i.e., California was unaware of the claim's falsity before it was approved and paid); and (3) that Defendants acted with the requisite scienter (i.e., that Defendants intentionally and knowingly defrauded California).

1. Plaintiffs Have Not Sufficiently Alleged The Submission Of A False "Claim."

The CFCA unequivocally requires that alleged fraud be tied to the submission of a false *claim*. CAL. GOV'T. CODE §§ 12651(a)(1) & (2) and (8); *see, e.g., United States ex rel. Hopper v. Anton*, 91 F.3d. 1261, 1265-66 (9th Cir. 1996) (explaining that the essential element of a FCA claim is the existence of a false claim). The only claims that are at issue in this litigation are the claims submitted by providers to Medi-Cal for reimbursement. (*See* Compl. ¶ 37.) Plaintiffs have not alleged that any information in these claim forms is false. (*See* Mot. to Dismiss at 16-18.) Indeed, Plaintiffs have not even alleged that these forms contained AWPs or DPs -- nor could they, because these forms contained only providers' charges. Without an adequate allegation that these submitted *claims* were false, as a matter of law, there can be no liability under the CFCA. *See People v. Duz-Mor Diagnostic Lab., Inc.*, 68 Cal. App. 4th 654, 672-73 (1998) (claim is not false when submitted in accordance with government directions).

Plaintiffs' response to this simple point is two-fold. *First*, Plaintiffs argue that they need not allege a false "claim"; any fraud in the abstract will suffice to state a CFCA claim. But that

is transparently wrong, as shown by the authorities cited above, the language of the statute, and the statute's very title -- the California *False Claims* Act. Even Plaintiffs' authorities confirm as much. For example, while Plaintiffs snip dicta from *United States v. Neifert-White Co.*, 390 U.S. 228 (1968), they neglect to mention that, in that case, the Supreme Court's holding tackled a "narrow and precise" question: "[d]oes the False Claims Act reach 'claims' for favorable action by the Government upon applications for loans or is it confined to 'claims' for payments due and from the Government?" *Id.* at 230. Interpreting the version of the FCA in force in 1968, the Supreme Court concluded that the defendant violated the FCA by creating false invoices to be submitted to a federal agency in support of loan applications seeking money from that agency. *Id*. at 230, 233. Thus, *Neifert-White* properly centered on the submission of a false claim. Similarly, in both *United States v. President & Fellows of Harvard College*, 323 F. Supp. 2d 151 (D. Mass. 2001) and *City of Pomona v. Superior Court*, 89 Cal. App. 4th. 793 (Cal. App. 2001), plaintiffs alleged submission of actual false claims -- indeed, the very passage from *City of Pomona* that Plaintiffs cite specifically ties liability "to the submission of false claims to governmental entities." (Resp. at 11.)[3]

Second, as a fallback, Plaintiffs half-heartedly assert that they have, in fact, "alleged the submission of false claims throughout the FAC." (Resp. at 12.) Not so. While Plaintiffs cite a span of over 125 paragraphs of their Amended Complaint in support of this assertion, none of these paragraphs describes a false claim. Instead, in these allegations, Plaintiffs merely repeat (again and again) their charge that the AWPs and DPs for Defendants' drugs published by

[3] Plaintiffs' use of *Harvard College* and *City of Pomona* indicates they have confused two separate requirements of the CFCA: (1) the existence of a false claim, and (2) the requirement that defendants *be sufficiently involved in the submission* of that false claim. Both *Harvard College* and *Pomona* address the latter point. Defendants' role (or, more accurately, lack thereof) in the claims submission process is discussed in Section II.B.1., *infra.*

pricing compendia Medi-Cal chose to use were not equal to the "actual" prices (net all discounts) typically paid by providers. Even taking these charges as true, they show at best false *statements* by Defendants to pricing compendia; they do not, however, allege any false *claim* submitted to Medi-Cal. They are, thus, inadequate to state a claim under the CFCA.

2. Plaintiffs Have Not Alleged That "AWP" Or "DP" Is False.

Even if AWP or DP could properly be considered a "claim" (and neither can), Plaintiffs would have a second problem: They have not alleged, and cannot allege, that these published list prices were "false." (*See* Mot. to Dismiss at 18-22.)

Plaintiffs concede, as they must, that California law defines AWP and DP to be the prices listed in pricing compendia. *See* Resp. at 16; *see also* CAL. WELF. & INST. CODE § 14105.45. Plaintiffs do not (and cannot) point to any law or regulation, California or federal, requiring that these prices mean something specific, like a discounted or average actual paid price. Rather, as set out above, California merely took the AWPs and DPs listed in the compendia as it found them and adopted these prices wholesale as its reimbursement benchmarks. That alone dooms their CFCA claims.

Plaintiffs' responses on this point are scattershot; none remotely hits the mark. *First*, Plaintiffs wildly assert that AWP and DP "are defined by reference to the Estimated Acquisition Cost (EAC) of a drug product." (Resp. at 15.) But that is exactly backwards. Federal law defines EAC as *California's* best estimate of providers' acquisition cost of the drugs. *See* 42 C.F.R. § 447.301. California, in turn, adopted AWP minus a percentage[4] and DP as its "best estimate" -- taking them as it found them in the pricing compendia, with no further definition. CAL. WELF. & INST. CODE § 14105.45 (defining AWP and DP as prices listed in compendia).

[4] The fact that California discounted AWP also proves that California knew that AWP did not itself constitute EAC.

Second, Plaintiffs urge the Court to "ascertain whether there is a reasonable, practical" alternative "interpretation" of AWP and DP "that should govern." (Resp. at 17-18 (citing *United States v. Data Translation, Inc*., 984 F.2d 1256, 1260 (1st Cir. 1992).) But this makes no sense. If California wanted an alternative definition of AWP and DP to govern, it should have regulated one, rather than adopting these prices from the compendia without change.

Regardless, quite tellingly, Plaintiffs offer no single reasonable alternative meaning of California's regulation. Nor could they -- and this, perhaps, is the key point. The CFCA can be brought to bear only when a defendant, clearly apprised of the ground rules, submits a false claim. For that reason, courts have consistently held that there is no FCA liability when defendants are accused of submitting false information for terms that are ambiguous. *See United States ex rel. Cox v. Iowa Health Sys*., 29 F. Supp. 2d 1022, 1026 (S.D. Iowa 1998) (granting Rule 12(b)(6) motion in FCA case where plaintiff could point to no law or regulation requiring defendants to submit claims in the manner alleged); *United States ex rel. Gathings v. Bruno's, Inc*., 54 F. Supp. 2d 1252, 1259-60 (M.D. Ala. 1999) (granting Rule 12(b)(6) motion where defendants' interpretation of disputed term was deemed reasonable). If California's regulation simply adopting AWP and DP root and branch could be transmuted to mean some lower price, as California wants, it could be transmuted to mean any number of prices -- with no guidance at all as to which is the "correct" one.[5]

[5] Plaintiffs' authorities, again, are not to the contrary. In *United States ex rel. Oliver v. Parson Co.*, 195 F.3d 457 (9th Cir. 1999) and *United States v. Estate of Roger*, Civ. A. No. 97461, 2001 U.S. Dist. LEXIS 24914 (E.D. Tenn. June 28, 2001), the courts held only that their construction of a regulation controlled the question of falsity, and where a court's ultimate view of a regulation differs from that of the defendant's, the court's prevails. Here, of course, Plaintiffs have not offered any concrete view of the regulation different from that advanced by Defendants. And, in any event, both *Parson* and *Roger* hold that ambiguity of government regulations or statutes negates the scienter required for a violation of the FCA. *United States ex rel. Walker v. R&F Properties* is entirely inapposite; it merely held summary judgment improper where an issue of fact exists regarding whether a regulation is really ambiguous. *See* 433 F.3d at 1358.

Finally, Plaintiffs offer the bizarre assertion that by defining AWP and DP with reference solely to what is published by pricing compendia, California merely intended to indicate "the source DHS will use to locate reported drug prices." (Resp. at 15.) Plaintiffs then liken California's definitional regulations to a hypothetical property tax regulation that "directs that taxes are to be assessed based on the price that a homeowner reports has been paid for a property." (Resp. at 17.) Plaintiffs state that, in their hypothetical scenario, "a homeowner who lied about the price they paid for the property would not be able to defend that lie by claiming that price is defined as the price that they report, and therefore whatever they reported cannot be false." (*Id.*)

But Plaintiffs' hypothetical proves Defendants' point. The invented regulation defines the taxes to be paid not just based on the price that a homeowner reports, but on the price the homeowner reports *has been paid for a property*. Section 14105.45, on the other hand, defines AWP and DP as simply the price reported by the pricing compendia -- not the price reported by the pricing compendia *as the average price paid for drugs*. Had California wanted this result, it should have specified what AWP and DP mean -- as the hypothetical regulation does by tying home price to the "price . . . paid [by a homeowner] for the property" -- rather than simply taking them directly from pricing compendia. California had the means to do so, had it wished (and has done so with respect to other pricing terms). *See* CAL. WEL. & INST. CODE § 14105.45(a)(1) (defining "average sales price" to mean the average price paid by a customer); *id.* § 14105.31(b) (defining "best price" to mean prices paid by customers, inclusive of discounts). That California did not do so here speaks volumes.

3. California Knew That AWP And DP Exceeded Actual Cost And Acquiesced (And Continues To Acquiesce) In Reimbursement At Those Levels.

Even if AWP and DP could be thought to be a "claim" (they are not), and even if they could be thought to be "false" (they cannot), Plaintiffs' CFCA claims would fail for a third reason: There can be no liability under the CFCA where, as here, the State has knowledge of the pertinent facts. (*See* Mot. to Dismiss at 22-24.) Here, California's knowledge that AWP and DP exceeded Medi-Cal providers' actual acquisition costs -- demonstrated extensively by the regulatory and statutory history, as well as the public record -- defeats Plaintiffs' CFCA claims as a matter of law for two reasons: (1) it defeats the falsity of the claim required by the CFCA; and (2) it precludes the possibility that Defendants acted with the requisite scienter required by the Act. *See Am. Contract Servs. v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854, 864 (Cal. App. 2001) (finding that "government's knowledge effectively negates the fraud or falsity required by the FCA") (citations omitted).

Plaintiffs' binary response on this point is telling. *First*, Plaintiffs spend several pages of their Response brief -- and an entire separate brief -- imploring this Court to ignore the public record. Strikingly, though, nowhere in Plaintiffs' extended plea do they actually deny that California was aware that AWP and DP exceeded actual cost. As set out in Defendants' response to Plaintiffs' separate brief, this Court need not put its head in the sand. And, in any event, even if the Court were to ignore the public record and focus only on the pleadings filed in this case, it is clear that California was apprised of the disparity between AWP and DP and actual cost since at least 1998 when Ven-A-Care first filed this case. (*See* Mot. to Dismiss at 24 n.12.)

Second, Plaintiffs try to graft onto the government knowledge doctrine a novel "affirmative government action" requirement. (Resp. at 7-8.) Whatever the scope of that requirement (and Plaintiffs are vague on the point), if it exists in the authorities Plaintiffs cite, it

is clearly satisfied here. Here, like the government did in *United States ex rel. Durcholz v. FKW, Inc.*, California knew that AWP and DP published by pricing compendia did not represent actual cost to various providers and thus (according to California) were "false," yet it approved and paid claims using those terms anyway. *See* 189 F.3d 542 (7th Cir. 1999). California cannot honestly claim that it "[received] something less than or different from that which it expected" when it chose to use AWP and DP in determining reimbursement to providers. *Id.* at 544-45; *see also United States ex rel. Butler v. Hughes Helicopters*, 71 F.3d 321, 327 (9th Cir. 1995). And, as in *American Contract Services*, any "defect" in the methodology of reimbursement based on AWP and DP arose solely from California's choice to take those terms, without further definition, as it found them in industry compendia. *See* 94 Cal. App. 4th 854, 865.

Even if there had been lingering uncertainty on California's part (and there was not), it was shattered when, during negotiations for supplemental rebates, Defendants provided California with their actual sales prices. Armed with that information, California cannot plausibly claim to have been in the dark about the disparity between AWP and DP on the one hand, and actual sales prices on the other. That, too, destroys Plaintiffs' CFCA claims. *See Shaw v. AAA Eng'g & Drafting Inc.*, 213 F.3d 519, 534 (10th Cir. 2001) (noting that discussions regarding the subject matter that formed the basis for the false claims may preclude liability); *Butler*, 71 F.3d at 327 (holding that defendants' "dialogue" with the government precluded a finding of the requisite intent required by the FCA).

B. Plaintiffs' Claims Are Defective For Other Reasons.

Even if Plaintiffs could properly allege the three elements of falsity, their claims are defective in other respects. For these reasons, too, they must fail.

1. Defendants Were Sufficiently Removed From The Claims Submission Process to Preclude, As A Matter Of Law, A Finding Of Liability Under Counts I And IV Of The Amended Complaint.

To state a cause of action under Counts I and IV of the Amended Complaint, Plaintiffs must allege that Defendants *presented or caused to be presented a false claim* for payment or approval. (*See* Mot. to Dismiss at 24-26.) To properly plead that Defendants "cause[d]" the presentation of a false claim, Plaintiffs must allege that Defendants had some degree of participation in the claims process. *See United States ex rel. Kinney v. Hennepin County Med. Ctr.*, No. Civ. A. 971680, 2001 U.S. Dist. LEXIS 25475 (D. Minn. Aug. 22, 2001); *see also United States ex rel. Shaver v. Lucas W. Corp.*, 237 F.3d 932, 934 (8th Cir. 2001). Plaintiffs' explicit plea for "[a]ll reasonable inferences" on this point (Resp. at 15) only underscores that their Amended Complaint fails to satisfy this requirement, as a matter of law or even logic.

On the law, Plaintiffs have failed to distinguish Defendants' authorities -- and Plaintiffs' authorities are inapposite. Plaintiffs pin their hopes on *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 52-53 (D. Mass. 2001) (Saris, J.) (*Parke-Davis I*), and *United States ex rel. Franklin v. Parke-Davis*, No. Civ. A. 9611651, 2003 U.S. Dist. LEXIS 15754 (D. Mass. Aug. 22, 2003) (Saris, J.) (*Parke-Davis II*) (collectively the "*Parke-Davis* cases"). The *Parke-Davis* cases involved a relator's allegations that defendant (a drug manufacturer) marketed off-label uses for its drugs to providers; that the drugs were not eligible for Medicaid reimbursement when used in those ways; and that the defendant's sales force coached providers on how to conceal the off-label nature of the prescription on claim forms in order to be able to submit claims for Medicaid reimbursement. *Parke-Davis I* held that these allegations, when accepted as true, were sufficient to survive a motion to dismiss because they tended to show that the provider's submissions of false claims were a foreseeable and intended consequence of its actions. *See* 147 F. Supp. 2d at 52-53. *Parke-Davis II*, in turn, concluded that the relator had

presented enough evidence on whether the defendant's conduct was a *substantial factor* in causing providers to submit false claims to survive summary judgment. *See* 2003 U.S. Dist. LEXIS 15754 at *15.

These cases, however, are easily distinguished. Far from alleging that Defendants here coached providers on how to fill out Medi-Cal claims, Plaintiffs have not alleged *any connection at all* between Defendants' reporting of list prices to third-party pricing compendia, on the one hand, and providers' filling out of claims, on the other. Nor could they: Providers submit claims based on their *charges*; it was California that decided to pay based on AWP or DP and it was California that chose the source from which to obtain the AWP and DP information. (Resp. at 13; *see* Compl. ¶ 37.) Because any allegedly "false" statements by Defendants in connection with the list prices the Defendants reported to third-party pricing compendia are, thus, entirely irrelevant to the content of providers' claims, the *Parke Davis* line simply has no bearing here. *See Parke-Davis II*, 2003 U.S. Dist. LEXIS 15754 at *16 (distinguishing *Kinney* on that ground).

As to logic, Plaintiffs claim (with no support) that in this case "no intervening force exists such as the independent actions of pharmacists and physicians." (*Id.*) The claim is fantastic. As set out above, it is *exactly* the independent actions of pharmacists and physicians that "cause" the submission of claims to California -- and Plaintiffs' own complaint says as much. (Resp. at 13; *see* Compl. ¶ 37.) Defendants have no control, whatsoever, over what providers submit in those claims. Thus, Counts I and IV are also defective as to "caus[ing]" submission of false claims, and must be dismissed for that reason as well.

2. Plaintiffs Misinterpret The Scope Of CAL. GOV'T CODE § 12651(a)(8).

In Count III, Plaintiffs allege a violation of California Government Code § 12651(a)(8), which imposes liability on (1) "beneficiaries" of an inadvertent submission of a false claim, if (2) they subsequently discover the falsity of that claim, and (3) fail to disclose its falsity to the

relevant authorities within a reasonable time. CAL. GOV'T CODE § 12651(a)(8). Defendants, however, are neither "beneficiaries," nor did they "discover" any false claims. These truths doom Count III. (*See* Mot. to Dismiss at 26-27.)

First, as to "discover[y]," Plaintiffs candidly admit that Defendants did not "discover" any false claims here; indeed, they boldly argue that "[i]t was not necessary for Defendants to 'discover' the falsity of the claims at issue here . . . ." (Resp. at 24.) The statute, however, plainly requires otherwise. That alone defeats Count III.

Second, as to "beneficiaries," Plaintiffs shoot at a straw person. They (mis)construe Defendants as arguing that CFCA liability *only* extends to "beneficiaries" who are the "actual recipient of government funds." (Resp. at 22.) Not so. Defendants merely posit that the term "beneficiary" as used in this subsection of the CFCA cannot be read as anyone who indirectly benefits from a government payment -- the meaning Plaintiffs urge in their Response. (*See* Resp. at 23.) Not only would such an interpretation impose liability on an almost unlimited number of people, but it also is nonsensical when taking into consideration the CFCA as a whole.

As Plaintiffs advocate, "[s]tatutory language must [] be construed in the context of the statute as a whole and overall statutory scheme." (Resp. at 23 (*quoting People v. Briceno*, 34 Cal. 4th 451, 459 (Cal. 2004).) Every other section of the CFCA uses only the term "person" when describing the actor that is subject to liability under the CFCA. *See* CAL. GOV'T CODE § 12651(a) ("*Any person* who commits any of the following acts . . .") (emphasis added). Section 12651(a)(8), however, limits the scope of the term "person" by including an additional requirement that the "person" also be a "beneficiary." If the Court interprets beneficiary as any person who may possibly benefit from the act, it would effectively eliminate that purposefully

inserted element of this particular cause of action under the CFCA. For these reasons, too, Count III must fail.

3. Plaintiffs' CFCA Causes Of Action Premised On Violations of the California Anti-Kickback Statute (Counts IV And V) Should Be Dismissed.

Counts IV and V allege that Defendants violated the CFCA by violating California's anti-kickback statute (CAL. WELF. & INST. CODE § 14107.2). The statute is pre-empted by federal law and is thus unconstitutional. A Florida anti-kickback statute materially identical to the California anti-kickback statute was recently found unconstitutional. (Mot. to Dismiss at 29-31); *see Florida v. Harden*, 873 So. 2d 352, 355 (Fla. Dist. Ct. App. 3d Dist. 2004). Plaintiffs have no persuasive answer as to why the California anti-kickback statute should not be similarly stricken -- other than to simply state that the Florida court was wrong. (Resp. at 30) But, as even Plaintiffs concede, the principles announced in *Harden* were reaffirmed by a Florida appellate court in *Florida v. Rubio*, 917 So. 2d 383 (Fla. Dist. Ct. App. 5th Dist. 2005). Plaintiffs also essentially concede (as they must) that the "safe harbor" provision of the federal anti-kickback statute is broader than that of the California anti-kickback statute -- which was the primary reason why the Florida anti-kickback statute was held unconstitutional. (Resp. at 31)

Even if the California statute was constitutional, Plaintiffs have not sufficiently alleged how Defendants violated it -- let alone how such a violation would state a CFCA claim. (*See* Mot. to Dismiss at 28-29.) Reporting allegedly inflated drug prices to pricing compendia is not an "offer" or "payment" to purchasers of pharmaceuticals from Defendants. *See United States v. Duz-Mor Diagnostic Lab., Inc.*, 650 F.2d 223, 227 (9th Cir. 1981) (stating that an "offer" requires the expressing of an *ability* to pay). Further, Plaintiffs cannot argue that Defendants' actions in giving discounts to providers, which Plaintiffs argue caused the existence of the "spread" -- *i.e.*, the alleged "illegal remuneration" -- violated the anti-kickback statute because

the anti-kickback statute contains a safe-harbor that specifically authorizes Defendants to provide such discounts.[6] CAL. WELF. & INST. CODE § 14107.2(c)(2).

Perhaps Plaintiffs' best run at this statute is an argument, raised in their Response, that *California* is actually the entity that gave the illegal kickback to providers as part of Defendants' fraudulent scheme. (Resp. at 26.) Defendants, the argument goes, "offered" Medi-Cal reimbursement to providers in exchange for their purchase of Defendants' drugs. Plaintiffs fail, however, to explain how Defendants are in a position to "offer" Medi-Cal reimbursement.

Moreover, a violation of the California anti-kickback statute cannot, by itself, form a basis for a CFCA claim. In their Response, Plaintiffs appear to be arguing for a sort of "implied certification" theory -- specifically, that the providers' submitted claims were false because providers impliedly certify that their claims are not tainted by kickbacks when providers did, in fact, accept kickbacks.[7] Under this apparent theory, violation of the anti-kickback statute is, at the same time, violation of the CFCA. But the theory cannot be applied here.

At least one court has explicitly rejected this theory with respect to anti-kickback statutes. *See United States ex rel. Barmak v. Sutter Corp.*, 2002 U.S. Dist. Lexis 8509, *15-18 (S.D.N.Y. May 14, 2002) (granting motion to dismiss and rejecting the implied certification theory with respect to an anti-kickback statute and the federal False Claims Act); *see also Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 778 n.8 (4th Cir. 1999) (noting that the implied certification theory for liability under the federal False Claims Act is "questionable"). Furthermore, even if the theory were viable as to the anti-kickback statute at issue here, it only

[6] Plaintiffs' Amended Complaint makes no allegations that this safe-harbor should not apply. For example, Plaintiffs make no allegations that providers were required to disclose all discounts received on claims submitted to California.

[7] The Amended Complaint does not explicitly contain any implied certification allegations.

applies "in *limited* circumstances." *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) (emphasis added). Two prerequisites must be satisfied; neither exists here.

First, the statute or regulation allegedly violated must *expressly predicate* payment upon compliance with that statute or regulation. *See Straus*, 274 F. 3d at 699. But the California anti-kickback statute does not expressly condition Medicaid payments upon compliance with that statute. And unlike the *Medicare* provider agreements described in the cases cited by Plaintiffs, Medi-Cal provider agreements do not expressly condition payment of a claim on compliance with the anti-kickback statute.[8]

Second, the government must have *relied* on the implied certifications in making payments to providers. In other words, the government must plead and prove that, had it known of the violation of the statute or regulation, it would not have paid the claim. *See United States ex rel. Bidani*, 264 F. Supp. 2d 612, 615 (N.D. Ill. 2003). That is simply not true here: not only *would* California have paid the providers' claims had they known that providers were receiving discounts and rebates from manufacturers, California *did* in fact pay such claims. Even today, California continues to approve and pay claims at amounts that it knows exceed providers' acquisition cost for Defendants' drugs. For these reasons too, Counts IV and V fail.

C. Plaintiffs Fail To State A Claim For Drugs That Were Reimbursed On Any Basis Other Than AWP Or DP.

Finally, to the extent Plaintiffs seek to recover for reimbursements made by Medi-Cal based on MAIC or FUL, the allegations must be dismissed. Plaintiffs' Amended Complaint hinges on two premises: (1) Medi-Cal's use of allegedly false AWPs and DPs; and (2) Defendants' alleged marketing of the "spread" to induce providers to purchase their drugs. (*See*

[8] A copy of the Medi-Cal Provider Agreement can be found on the Medi-Cal website at http://files.medi-cal.ca.gov/pubsdoco/provappsenroll/02enrollment_DHS6208.pdf (last visited on April 2, 2006).

Compl. ¶ 1.) Neither of these premises holds true, however, when Medi-Cal reimburses based on MAIC or FUL.

First, Plaintiffs fail in their attempt to connect the allegedly fraudulent AWPs and DPs to the calculation of MAIC and FUL. Plaintiffs acknowledge that the FUL is set based on the lowest price in the compendia, which is then multiplied by 150%, and that in certain instances the FUL was based on WAC, not AWP or DP. (Resp. at 32.) Similarly, Plaintiffs concede that, from September 2002 to September 2004, MAIC was calculated based on "wholesale selling prices" obtained from distributors selected by California and not AWP or DP. (Resp. at 34 n.23.) And prior to 2002, Plaintiffs explain that California determined MAIC as AWP-5% of a *reference* drug. (Resp. at 24.) But nowhere in their Amended Complaint do Plaintiffs allege that "reference drug" is one of Defendants' drugs for which California has alleged wrongdoing.[9]

Second, reimbursement based on MAIC and FUL apply a single reimbursement amount to any manufacturer's version of that drug. Thus, no single defendant could "increase their market share" by manipulating and marketing its AWP or DP because any resulting effect (if there is one) on reimbursement would apply to every company's product, regardless of its published AWP or DP. (Compl. ¶ 44.) Accordingly, if a drug is reimbursed on a basis other than AWP or DP, then claims as to those drugs should be dismissed.

III. THE AMENDED COMPLAINT DOES NOT COMPLY WITH RULE 9(b).

As set out above, each of Plaintiffs' five Counts is substantively defective -- most in multiple ways. Each should, therefore, be dismissed under Rule 12(b)(6) for failure to state a

[9] Plaintiffs mistakenly assert that this issue raises a damages question not to be determined on a motion to dismiss. It is axiomatic, however, that failure to plead an element of a claim is grounds for dismissal on a Rule 12(b)(6) motion. *See Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 738 (9th Cir. 1987) ("The purpose of F. R. Civ. P. 12(b)(6) is to enable defendants to challenge the legal sufficiency of complaints without subjecting themselves to discovery") (internal citations omitted). Because Plaintiffs have not plead both the elements of causation and damage for drugs reimbursed at MAIC or FUL, it is wholly appropriate and necessary for these claims to be dismissed.

claim on which relief can be granted. At a minimum, however, these counts are also procedurally defective because they fail to comply with the strictures of Rule 9(b). (Mot. to Dismiss at 11-14.) Rule 9(b) requires that, not only must the allegations surrounding the underlying fraudulent scheme be plead with particularity, but also the *false claims* -- "that constitute the essential element of an FCA qui tam action" -- must be pled with particularity. *See United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004). Because Plaintiffs have failed to do so, the Court should dismiss all counts.

Plaintiffs essentially concede that the standards articulated in Defendants' Motion to Dismiss are accurate but argue that they have been met. Alternatively, Plaintiffs argue that Rule 9(b)'s requirements are relaxed in complex and far-reaching cases, such as this one. (*See* Resp. at 35-36.) Plaintiffs are wrong on both accounts.[10]

First, contrary to Plaintiffs' assertions, the Amended Complaint does not adequately describe the "who, what, when, where and how" of Defendants' conduct in violation of the CFCA. On page 36 of their Response, Plaintiffs attempt to explain how they alleged the "who, what, when, where and how" of the *underlying fraudulent scheme*,[11] but ignore the "who, what,

[10] Additionally, Plaintiffs' assertion that they have somehow complied with a Rule 9(b) "safe-harbor" established by this Court for *In re Pharmaceutical Industry Average Wholesale Pricing Litigation* cases by identifying the specific drugs sold by each Defendants and their alleged fraudulent AWPs is misplaced. This Court has not addressed Rule 9(b) in the context of a case based solely on FCA causes of action.

[11] Plaintiffs' explanation regarding the "who, what, when, where and how" of the underlying fraudulent scheme is also weak. They argue that the "what" are the fraudulent AWPs or DPs published *by* the pricing compendia. In the Amended Complaint, however, Plaintiffs allege that the "what" are Defendants' statements *to* the pricing compendia. (Compl. ¶ 36.) Contrary to Plaintiffs' statement in their Response, these are not synonymous. Additionally, the "when" is a period that spans over a decade. This is a far greater amount of time than the 5-month period relator identified in *Parke-Davis I* that this Court found was sufficient for Rule 9(b) purposes. *Parke-Davis*, 147 F. Supp. 2d at 44, 48. Finally, Plaintiffs do not adequately explain "how" Defendants' alleged false representations to FDB would cause otherwise truthful claims to be false. (*See* Resp. at 36.)

where, when and how" of the *false claims* submitted to the government, as required by *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005).[12]

Moreover, Plaintiffs have not satisfied the *Karvelas* test. Plaintiffs argue that the Amended Complaint's exhibits satisfy the *Karvelas* test because, in addition to providing the NDC numbers for Defendants' drugs, they provide "the amount of money charged by the providers to the government." (Resp. at 27.) This is flat wrong. Plaintiffs' exhibits list the "Cost of the Drug Product" or CDP, which represents "California's reimbursement price" -- not the amount billed by the provider (or the claim). (*See* "Glossary for Exhibit Headings," Compl. Exs.)[13] Even if Plaintiffs' assertion about their exhibits was correct, however, these two factors, alone, do not satisfy the test set forth in *Karvelas*. It is no wonder, therefore, that Plaintiffs argue, in the alternative, that they should not be held to the *Karvelas* standard.

Second, *Parke-Davis I* does not excuse Plaintiffs from particularly identifying the false claims. In *Parke-Davis I*, this Court held that the relator in that case met Rule 9(b)'s requirements by alleging the "who," "what," "when" and "how" of the alleged fraud scheme without actually alleging specific false claims. *See* 147 F. Supp. 2d at 49. The Court's decision, however, turned on the unique fact that the relator in *Parke-Davis I* did not "reasonably have pre-discovery access to that patient-specific information." *Id.* Indeed, the Court recognized, "To be sure, when a [plaintiff] has access to the information regarding the alleged false claims merely

[12] Plaintiffs' attempt to distinguish this case from *Corsello* fails. Plaintiffs argue that their "allegations surrounding Defendants' fraudulent scheme, provide a factual basis to conclude that false claims were actually submitted to the government." (Resp. at 37.) Simply making that conclusory statement does not make it so. Indeed, the "factual" basis given by Plaintiffs is no stronger than that held insufficient for purposes of Rule 9(b) in *Corsello*. *Corsello*, 428 F.2d at 1014 (holding that "the submission [of the false claim] must be pleaded with particularity and not inferred from the circumstances").

[13] It is also difficult to understand how California could arbitrarily assign a universal CDP to each Defendants' drug when CDP is supposedly determined on a claim by claim basis as the lower of EAC, FAC, MAIC, or the amount billed by the provider. *Id.*

alleging a fraudulent scheme may not be sufficient." *Id.* Here, Plaintiffs undisputedly have access to the alleged false claims, yet they refuse to describe even one -- let alone how such claim is fraudulent.

To escape their Rule 9(b) obligations, Plaintiffs point to the sheer volume of the number of claims at issue, and argue that it would be impossible to attach every single claim. (Resp. at 37-38.) This, however, is a red herring. Defendants do not contend that Plaintiffs must attach every single alleged "false" claim to satisfy Rule 9(b). Rather, Defendants contend that Plaintiffs must satisfy the *Karvelas* test, which requires Plaintiffs to describe with particularity *at least some* of the allegedly false claims as to each Defendant and how the information contained in those claims is false. *See Karvelas*, 360 F.3d at 233.

Plaintiffs' desperate pleas to this Court to not require them to describe the actual false claims or, at the very least, attach a few representative samples, should give the Court pause. Plaintiffs are concerned that these claims will reveal to the Court what they already know -- that the contents of those claims will prove, as a matter of law, that Plaintiffs' Amended Complaint should be dismissed in its entirety.[14]

CONCLUSION

For the reasons stated above, and in Defendants' Memorandum Of Law In Support of Their Motion to Dismiss, the Defendants respectfully request that Plaintiffs' First Amended Complaint-In-Intervention be dismissed in its entirety.

[14] Plaintiffs' failure to plead with particularity allegations constituting a single violation of California's anti-kickback statute provides additional grounds why Counts IV and V should be dismissed. Plaintiffs' explanation of how they satisfied Rule 9(b) in these counts is confusing at best. They argue that the illegal remuneration that was paid to providers was, in fact, paid by California. Yet they further argue that they are excused from complying with Rule 9(b) in this instance because the facts surrounding the illegal remuneration paid *by California* to providers is peculiarly within Defendants' control. (Resp. at 39.) Plaintiffs' argument is nonsensical. If California is the party paying the illegal remuneration, how can it not be informed of the specifics of that remuneration?

Dated: April 3, 2006

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on April 3, 2006, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Tara A. Fumerton
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